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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,097	06/14/2001	Anton Wellstein	102728-P01-004	3830

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EXAMINER

KOLKER, DANIEL E

ART UNIT PAPER NUMBER

1649

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/880,097		WELLSTEIN, ANTON	
	Examiner		Art Unit	
	Daniel Kolker		1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/11/06, 10/12/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 95,96 and 98-118 is/are pending in the application.
- 4a) Of the above claim(s) 106-118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 95,96 and 98-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 95-96,98-118 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's remarks, amendments, and declarations filed 11 August 2006 and 12 October 2006 have been entered. Claims 95 – 96 and 98 – 118 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 August 2006 has been entered.

Election/Restrictions

4. Claims 106 – 118 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2 February 2004.

Claims 95 – 96 and 98 – 105 are under examination.

Withdrawn Rejections and Objections

5. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejections under 35 USC 112, first paragraph, are withdrawn in light of the amendments.

B. The rejections under 35 USC 112, second paragraph are withdrawn in light of the amendments.

C. The rejection under 35 USC 102(b) over the reference by Aigner et al. is withdrawn in light of the arguments and declaration.

D. The objection to claim 97 for being duplicative of claim 96 is moot, as claim 97 is canceled.

Maintained Rejections***Claim Rejections - 35 USC § 102***

6. Claims 95 – 96, 98, and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris (U.S. Patent 5,770,421, of record).

This rejection is maintained for the reasons set forth previously and explained below. Morris teaches the extracellular domain of human ALK comprises the first 1030 residues of the peptide, including the signal sequence (see column 26 lines 62 – 66). Morris explicitly claims an isolated polypeptide comprising residues 27 – 1030 of ALK (see Morris, claim 5). This is clearly “a portion but not all of the extracellular domain” as recited in claim 95. Applicant argues, on pp. 9 – 10 of the remarks, that Morris identifies only a putative extracellular domain and thus does not anticipate the claimed invention. Applicant’s arguments have been fully considered but they are not persuasive. Morris teaches and even claims a protein which is part, but not all of, the extracellular domain. The extracellular domain begins at the N-terminus and extends to about residue 1030. See Morris, column 26, as well as Figure 1a from the instant application. Note that Figure 1a indicates that the ECD (extracellular domain) begins at residue number 1 and continues up to the TM (transmembrane domain). Morris teaches the extracellular domain includes the signal sequence, and then goes on to claim that portion of the extracellular domain that lacks the signal sequence. Whether or not Morris identifies the domains as “putative” or not does not seem particularly relevant, as the product taught and claimed by Morris is within the scope of instant claim 95. Claim 96 is rejected as the protein is soluble. Note that Morris et al. also teach removing insoluble matter during the purification of their protein (see column 32 lines 10 – 24), and therefore since it is not insoluble it is, by definition, soluble, and meets the limitation of claim 96. Claim 98 is rejected because it is not limited to proteins consisting of amino acids 368 – 447, but rather to proteins “consisting essentially of” these residues. This open claim language allows for inclusion of additional elements so long as they do not materially affect the recited product. Here, the additional amino acids do not materially affect the product as it would still be expected to produce an immunogenic response when administered to animals. Claim 101 is rejected as the composition claimed therein requires no elements beyond the polypeptide.

New Rejections***Claim Rejections - 35 USC § 112***

7. Claims 95 – 96 and 98 – 105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 95 was not originally-presented, but was added in the amendment filed 16 March 2005. In the accompanying remarks, applicant directed the examiner's attention to pp. 3, 4, 9, and 10 of the originally-filed specification as supporting the newly-added claim. While these sections do identify various regions of the ALK protein, such as the PTN-binding region, the examiner is unable to find support for "a polypeptide comprising a portion but not all of the extracellular domain" of ALK as recited in claim 95. Note that on p. 3 of the specification and in originally-filed claims 10 – 11, applicant had contemplated proteins comprising one or more but not all regions of the ALK protein. The examiner is unable to find support for proteins which comprise a portion, but not all, of the extracellular domain. The remaining claims all depend from claim 95 and thus are rejected as well.

8. Claim 101 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 101 depends from claim 97, but claim 97 is canceled. The skilled artisan would not be able to determine the metes and bounds of the claim, as it depends in part from a canceled claim.

Claim Rejections - 35 USC § 102

9. Claims 95 – 96, and 101 – 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Coughney et al. (1999. Journal of Chromatography B: Biomedical Sciences and Applications 728(1):49-57, cited on IDS filed 20 July 2004). Note the enclosed printout from the journal's website indicates the reference was posted on the internet, and thus publicly available, 13 May 1999. Therefore the reference is prior art under 102(b).

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Caughey teaches a polypeptide consisting of residues 280-480 of ALK (see p. 50, second column, first complete paragraph). The reference does not disclose the actual sequence used, but it appears to be identical to that of claim 1. The protein comprises a portion of, but not all of, the extracellular domain of ALK. Claim 96 is rejected as the reference by Coughy teaches the protein is soluble in 8M urea (see top of p. 51). Claim 98 is rejected because it is not limited to proteins consisting of amino acids 368 – 447, but rather to proteins “consisting essentially of” these residues. This open claim language allows for inclusion of additional elements so long as they do not materially affect the recited product. Here, the additional amino acids do not materially affect the product, as it still is able to produce antibodies. Claim 101 is rejected as it depends from claim 95 and requires no additional elements. Claim 102 is rejected as the reference by Caughey teaches the pharmaceutically acceptable carrier 8M urea. Claim 103 is rejected as the reference teaches administration of 0.5 mg protein to rabbits, absent evidence to the contrary the dose appears to be within the scope of the claim as no specific ranges of therapeutically effective doses are recited.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

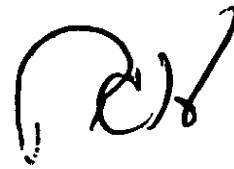
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.

October 18, 2006



ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER